

REMARKS

Entry of the present amendment with allowance of the application is respectfully requested in view of the present remarks.

Applicants express appreciation for the courtesies extended by the Examiner during a November 17, 2004 personal interview with Applicants' representative Arnold Turk.

During the interview, Applicants' invention as recited in the claims pending in the instant application were discussed. Following this discussion, the rejection of record in parent Application No. 09/807,980 of these claims (Office Actions mailed April 17, 2003 and October 31, 2003) was noted, and arguments were set forth with reference to Duncan et al. (hereinafter "Duncan"), Journal of Controlled Release, 19 (1992) 331-346 in conjunction with results shown in a Table for compounds with and without galactose residues.

Expanding upon the above, during the interview, a copy of Duncan was shown to the Examiner along with a Table showing results with and without galactose residues being present. As noted in the Interview Summary form, the Examiner noted that Duncan, especially its Table 3, shows that drug-polymer is more effective in treating liver cancer than drug-polymer-galactosamine.

Moreover, during the interview, the submission of a Declaration under 37 C.F.R. 1.132 including the Table discussed with the Examiner was also discussed to further show that Applicants' drug-polymer-galactose is more effective than drug-polymer in treating liver cancer, and stating that this result is unexpected in view of Duncan. The Examiner

indicated that such a Declaration would overcome the obviousness rejection set forth in the parent application based upon WO 97/46,260 as the primary reference.

In parent Application No. 09/807,980, in the Office Action mailed April 17, 2003 (and repeated in the Office Action mailed October 31, 2003), Claims 1-11, 14-20, 22 and 23 were rejected under 35 U.S.C. 103(a) as being obvious over WO 97/46260 (with EP 0 916 348 being used as an English translation of the international publication) in view of JP 6-87746 and Theodore et al. (U.S. Patent No. 5,886,143), Gonsho et al. ("Tissue-Targeting Ability of Saccharide-Poly(L-Lysine) Conjugates", Biol. Pharm. Bull., Vol. 17, No. 2, pp. 275-282 (1994)), Hashida et al. (Targeted Delivery of Drugs and Proteins to the Liver Via Receptor-Mediated Endocytosis. Journal of Controlled Release, 1997, Vol. 46, pp. 129-137), Kichler et al. (Versatile Synthesis of Bi- and Tri-Antennary Galactose Ligands, Glycoconjugate Journal, 1995, Vol. 12, pp. 275-281) or Nishikawa et al. ("Synthesis and Pharmacokinetics of a New Liver-Specific Carrier, Glycosylated Carboxymethyl-Dextran, and Its Application to Drug Targeting", Pharmaceutical Research, Vol. 10, No. 9, pp. 1253-1261 (1993)).

As noted above, during the above-noted interview the Examiner indicated that this ground of rejection would not be made in the instant application upon presentation of a Declaration Under 37 C.F.R. 1.132. Accordingly, Applicants are submitting herewith a Declaration Under 37 C.F.R. 1.132 of Yoshinobu Shiose.

Applicants respectfully submit that one having ordinary skill in the art would have recognized that before Applicants' invention, that saccharide modification of a conjugate compound of an antitumor agent bound with a polymer would not yield an improvement of

antitumor effect of the conjugate compound. Therefore, one of ordinary skill in the art would not have expected Applicants' advantageously high antitumor effect against liver cancer.

Applicants also submit herewith a copy of Duncan accompanied by a Form PTO-1449 listing the document. The Examiner is respectfully requested to initial the form and to forward an initialed copy of the form with the next communication from the Patent and Trademark Office.

Applicants further note that the specification has been amended herein in a manner similar to that in the parent application to more clearly indicate figures of drawings that are associated with the Examples, to even more clearly indicate the formulas in Examples 10 and 11, and to more clearly indicate a compound used in Example 7.

Also, in order that the record is clear, upon review of the Preliminary Amendment, it was noted that the amendments to the paragraph appearing at page 42, lines 10-28 were inadvertently indicated as page 39, line 2 to page 40, line 1. Since each of these paragraphs are amended in the present amendment, the record should presently be clear in this regard.

Moreover, as noted in the parent application, Applicants note that the compound shown in line 1 of Example 10 was obtained by the method described in WO 99/61061, and this information is once again being submitted in this continuation application to ensure that the record is complete.

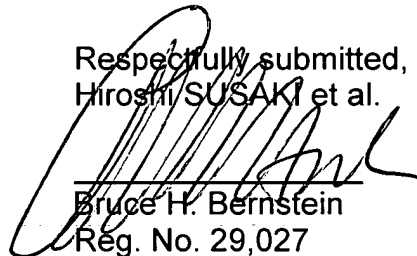
Still further, as discussed with the Examiner in the parent application and to ensure that the record is clear, Applicants note that the sequence identifiers are utilized in the

application to represent the spacers or the spacer portions of compounds as compared to the whole compound, and the Examiner indicated that this is acceptable even though the spacer is included in compounds.

As early mailing of the Notices of Allowance and Allowability is respectfully requested.

Should the Examiner have any further comments or questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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